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09/817,009	03/24/2001	Mark B. Lyles	068986.0103	5744

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BAKER BOTTS L.L.P.
PATENT DEPARTMENT
98 SAN JACINTO BLVD., SUITE 1500
AUSTIN, TX 78701-4039

EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/817,009	Applicant(s) LYLES, MARK B.	
	Examiner Jon D. Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-10,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-10, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/07 has been entered. Claims 1, 3, 4, 7-10, 13, and 14 were pending. Applicants amended claim 1. No claims were added or canceled. Therefore, claims 1, 3, 4, 7-10, 13, and 14 are still pending and examined on the merits.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Withdrawn Objections/Rejections

2. The rejection under 35 U.S.C. § 112, second paragraph is withdrawn in view of Applicants' amendments to claim 1. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claim Rejections - 35 USC § 103

3. Claims 1, 3, 4, 7-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glazer et al. (Glazer, M.; Frank, C.; Vinci, R. P.; Megali, G.; Fidanza, J.; Beecher, J. "High

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surface area substrates for DNA arrays” *Materials Research Society Symposium Proceedings* 1999, 576, 371-376) and Yasukawa, et al. (U.S. patent No. 5,629,186).

For **claim 1**, Glazer et al. (see entire document) disclose high surface area substrates for DNA arrays (see Glazer et al., abstract), which reads on claim 1. For example, Glazer et al. disclose two-dimensional arrays of biomolecules that contain at least 100 different molecules on a porous substrate at predefined regions (see Glazer et al., pages 371-2, Introduction; see also figure 1-2).

For **claims 10, 13 and 14**, Glazer et al. disclose both oligonucleotides and DNA (e.g., see Glazer et al., pages 371-2, Introduction). Although Glazer et al. does not explicitly disclose RNA, the reference does teach the genus oligonucleotides which only contains two possible species i.e., DNA or RNA and, as a result, the species RNA would be rendered obvious (e.g., see *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), wherein claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound). Here, the genus contains only RNA and DNA and they are closely related in structure because they only differ by one –OH group.

The prior art teachings of Glazer et al. differ from the claimed invention as follows:

For **claim 1**, Glazer et al. are deficient in that they do not teach a fused fiber porous material that is manufactured from alumina fibers, silica fibers, and a fusion source. Glazer et al. only recite porous materials that are 67.4% SiO₂, 25.7% B₂O₃ and

6.9% Na₂O (see Glazer et al., page 372, Experiment, Sodium borosilicate glass; see also page 372, paragraphs 2-4). Furthermore, the Glazer reference is deficient in that it does not specifically recite a pore radius e.g., greater than about 10 microns. Glazer et al. are also deficient in that they do not specifically recite the limitation that all of said material consist of a density of at least six pounds per cubic foot.

For **claims 3 and 4**, Glazer et al. are deficient in that it does not specifically recite that the porous material can comprise fused fibers of alumina, silica and a fusion source like boron. Furthermore, Glazer et al. also does not recite that the porous material can be made from a compositions comprising about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weigh boron. Glazer et al. only recites that materials that are 67.4% SiO₂, 25.7% B₂O₃ and 6.9% Na₂O (see Glazer et al., page 372, Experiment, Sodium borosilicate glass; see also page 372, paragraphs 2-4).

For **claims 7-9**, Glazer et al. are deficient in that it does not specifically recite the that the percentage of exposed surface is at least about 50%, 75% or 95% silicon dioxide.

However, Yasukawa, et al. teach the following limitations that are deficient in Glazer et al.:

For **claim 1**, Yasukawa et al. teach fused fibrous ceramic materials that are prepared from amorphous silica and/or alumina fibers with 2 to 12 % boron nitride (e.g., see Yasukawa, et al., abstract). Yasukawa et al. disclose the “silica fibers have ... fiber diameters between about 5 to 20 μm” (e.g., see column 1, lines 34-35 wherein 20 μm >>

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10 μm). Yasukawa et al. disclose the “silica fibers have ... fiber diameters between about 5 to 20 μm ” (e.g., see column 1, lines 34-35 wherein 20 μm >> 10 μm).

Yasukawa et al. do not explicitly state that their mean pore diameter is greater than 10 microns. However, the Examiner contends that this would be inherently disclosed by the reference because Yasukawa et al. teaches the same porous material composed from silica, alumina and boron wherein the composition by weight is about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weight boron (e.g., see Yasukawa et al., column 3, lines 66-67, “80 percent of fiber weight of silica fibers and 20 percent by fiber weight of alumina fibers”; see also column 2, lines 4-6, “boron nitride particles, in an amount between about 2-12 percent by weight of the total fiber weight”). In addition, Yasukawa et al. disclose that the density of all of said material is greater than six pounds per cubic foot (e.g., see claim 8; see also column 1, line 29). Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP § 2112.01. The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For *claims 3 and 4*, Yasukawa et al. teach porous materials with silica, alumina and boron wherein the composition by weight is about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weight boron (e.g., see Yasukawa et al., column 3, lines 66-67, “80 percent of fiber weight of silica fibers and 20 percent by fiber weight of alumina fibers”; see also column 2, lines 4-6, “boron nitride particles, in an amount between about 2-12 percent by weight of the total fiber weight”).

For *claims 7-9*, Yasukawa, et al. does not disclose the % silicon dioxide at the exposed surface, but the material is produced using the same alumina/silica fibers and the same boron source in the same proportions and, as a result, would be expected to possess the same % silicon dioxide at the exposed surface as that claimed by Applicants. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922-1923 (PTO Bd. Pat. App. & Int.).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the porous materials disclosed by Yasukawa et al. with the invention as disclosed by Glazer et al. because Glazer explicitly state that porous materials can be used to increase the number of immobilized probe molecules in DNA arrays (e.g., see Glazer et al, page 372, paragraph 2, “Porous surface layers are a potential

routes to increasing the signal from DNA arrays, as they increase the total surface area on which probes can be attached, and hence the capacity for bound target molecules”), which would encompass the porous materials disclosed by Yasukawa. In addition, a person of ordinary skill in the art would have been motivated to use the porous material disclosed by Yasukawa et al. because Glazer et al. states, “Inorganic surfaces have the advantage that they are similar to the original glass substrate, so that array fabrication protocols can be used”, which would encompass the “inorganic” silica/alumina fibers disclosed by Yasukawa et al. Yasukawa et al. also state that their matrix has “relatively larger pores” (e.g., see column 1, line 36) that liquid samples could more easily penetrate. In addition, a person of ordinary skill in the art would have reasonable expected to be successful because Yasukawa et al. state that the “silica fibers may be derivatized with molecules effective to bind ligand molecules passed through the matrix” (e.g., see column 1, lines 55-56; see also figures 13A-B; see also column 1, lines 49-50, “the matrix may be coated with a biocompatible material at its outer surface”), which would be required for the fabrication of a biological array.

4. Claims 1, 3, 4, 7-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (U.S. Pat. No. 5,959,098) (Filing Date is **April 17, 1996**) and Yasukawa, et al. (U.S. patent No. 5,629,186).

For *claim 1*, Goldberg et al (see entire document) disclose a substrate for the attachment of an array of greater than 100 different biomolecules bound to different predetermined regions of the surface of the porous material (see Goldberg et al., column

6, section IV), which reads on claim 1. For example, Goldberg et al discloses a two-dimensional array comprising molecules bound to the material surface (see Goldberg et al, column 6 lines 50-57, see also column 6 last paragraph). Goldberg et al also discloses that said material surface may be porous (see Goldberg et al, column 6, lines 39-49, “Silica aerogels may also be used as substrates ... Porosity may be adjusted by altering reaction conditions by methods known in the art”). Goldberg also discloses that at least 100 different molecules may be bound to the surface of the porous material in different predetermined regions (see Goldberg et al, column 2, lines 2-4, “Each polymer array includes a plurality of different polymer sequences coupled to the surface of the substrate wafer in a different known location”) (see also columns 9-14, section V; see especially column 10, last paragraph, “Using the above described methods, arrays may be prepared having all polymer sequences of a given length ... For an array of 8mer or 10mer oligonucleotides, such arrays could have upwards of about 65,536 and 1,048,576 different oligonucleotides respectively”).

For *claims 10, 13 and 14*, Goldberg et al discloses an array of oligonucleotides (see Goldberg et al, columns 9-14, section V; see especially column 10, last paragraph, “Using the above described methods, arrays may be prepared having all polymer sequences of a given length ... For an array of 8mer or 10mer oligonucleotides, such arrays could have upwards of about 65,536 and 1,048,576 different oligonucleotides respectively”), which anticipates claim 10. Furthermore, Goldberg discloses nucleic acids, a broad term, which would encompass both RNA and DNA. Furthermore, the chemistry for the solid-phase synthesis of both RNA and DNA via modification of the

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silanol groups is well known in the art. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The prior art teachings of Goldberg et al. differ from the claimed invention as follows:

For **claim 1**, Goldberg et al. are deficient in that they do not teach a fused fiber porous material that is manufactured from alumina fibers, silica fibers, and a fusion source. Furthermore, the Goldberg reference is deficient in that it does not specifically recite a pore radius e.g., greater than about 10 microns. Goldberg et al. only teach generally that the porosity may be adjusted using known methods in the art (see Goldberg et al., column 6, lines 39-49). Goldberg et al. are also deficient in that they do not specifically recite the limitation that all of said material consists of a density of at least six pounds per cubic foot.

For **claims 3 and 4**, Goldberg et al. is deficient in that it does not specifically recite that the porous material can comprise alumina, silica and boron. Furthermore, Goldberg et al. also does not recite that the porous material can be made from a compositions comprising about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weigh boron. Goldberg et al. only

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recites that that “[p]referred substrates generally comprise planar crystalline substrates such as silica based substrates” (see Goldberg et al., column 6, lines 30-31).

For **claims 7-9**, Goldberg et al. is deficient in that it does not specifically recite the that the percentage of exposed surface is at least about 50%, 75% or 95% silicon dioxide.

However, Yasukawa, ET AL. teach the following limitations that are deficient in Goldberg et al.:

For **claim 1**, Yasukawa et al. teach fused fibrous ceramic materials that are prepared from amorphous silica and/or alumina fibers with 2 to 12 % boron nitride (e.g., see Yasukawa, et al., abstract).

Yasukawa et al. do not explicitly state that their pore diameter is greater than 10 microns. However, the Examiner contends that this would be inherently disclosed by the reference because Yasukawa et al. teaches the same porous material composed from silica, alumina and boron wherein the composition by weight is about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weight boron (e.g., see Yasukawa et al., column 3, lines 66-67, “80 percent of fiber weight of silica fibers and 20 percent by fiber weight of alumina fibers”; see also column 2, lines 4-6, “boron nitride particles, in an amount between about 2-12 percent by weight of the total fiber weight”). In addition, Yasukawa et al. disclose that all of said material consists of a density of about six pounds per cubic foot (e.g., see claim 8; see also column 1, line 29). Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially

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identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP § 2112.01.

For **claims 3 and 4**, Yasukawa et al. teach porous materials with silica, alumina and boron wherein the composition by weight is about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weight boron (e.g., see Yasukawa et al., column 3, lines 66-67, “80 percent of fiber weight of silica fibers and 20 percent by fiber weight of alumina fibers”; see also column 2, lines 4-6, “boron nitride particles, in an amount between about 2-12 percent by weight of the total fiber weight”).

For **claim 5**, Yasukawa et al. disclose the “silica fibers have ... fiber diameters between about 5 to 20 μm ” (e.g., see column 1, lines 34-35 wherein 20 μm >> 10 μm).

For **claim 6**, Yasukawa et al. disclose that the matrix may have a density of 3.5 to 12 pounds per cubic foot which is “at least about” 6 pounds per cubic foot (e.g., see claim 8; see also column 1, line 29)

For **claims 7-9**, Yasukawa, et al. does not disclose the % silicon dioxide at the exposed surface, but the material is produced using the same alumina/silica fibers and the same boron source in the same proportions and, as a result, would be expected to possess the same % silicon dioxide at the exposed surface as that claimed by Applicants. “When the PTO shows a sound basis for believing that the products of the applicant and the prior

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art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the porous materials disclosed by Yasukawa et al. with the invention as disclosed by Goldberg et al. because Goldberg et al. explicitly state that “[p]referred substrates generally comprise planar crystalline substrates such as silica based substrates” (see Goldberg et al., column 6, lines 30-31), which would encompass the silica based substrates disclosed by Yasukawa et al. (i.e., the silica/alumina/boron substrates). In addition, a person of ordinary skill in the art would have been motivated to use the porous material disclosed by Yasukawa et al. because silica/alumina/boron substrate disclosed by Yasukawa et al. has “relatively larger pores” (e.g., see column 1, line 36) that liquid samples could more easily penetrate. In addition, a person of ordinary skill in the art would have reasonable expected to be successful because Yasukawa et al. state that the “silica fibers may be derivatized with molecules effective to bind ligand molecules passed through the matrix” (e.g., see column 1, lines 55-56; see also figures 13A-B; see also column 1, lines 49-50, “the matrix may be coated with a biocompatible material at its outer surface”), which would be required for the fabrication of a biological array.

Response

5. Applicant's arguments directed to the above 35 U.S.C. § 103(a) rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from its original version to more clearly address Applicant's newly amended and/or added claims and/or arguments.

Applicant argues that the rejection should be reconsidered in view of their amendments (e.g., see 1/29/07 Response, page 5).

The claims stand rejected for the reasons of record, which are incorporated in their entirety herein by reference. For example, the combined references teach the at least six pounds per cubic foot limitation that is currently claimed (e.g., see 2/23/06 Final rejection, response section starting on page 13, especially sections [2-3] quoting, for example, claim 8 disclosing 5.5-12 pounds per cubic foot, which meets the six pounds limitation). Therefore, Applicants' arguments are moot.

Accordingly, the 35 U.S.C. § 103(a) rejections cited above are maintained.

New Rejections

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 1, 3, 4, 7-10, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. **Claim 1** recites the limitation "said material" in lines 4-6. There is insufficient antecedent basis for this limitation in the claim. The Examiner recommends, "said porous material" as a replacement. Therefore, claim 1 and all dependent claims are rejected under 35 USC 112, second paragraph.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
April 9, 2007

JON EPPERSON
PRIMARY EXAMINER

